510(k) Summary
APTUS® Titanium Fixation System, Medartis, Inc.

ADMINISTRATIVE INFORMATION

Manufacturer Name:	Medartis, Inc. 127 W Street Road, Suite 203 Kennett Square, PA 19348 Telephone (610) 961-6101 FAX (610) 961-6108
Official Contact:	Kate Gehret
Representative/Consultant:	Floyd G. Larson PaxMed International, LLC 11234 El Camino Real, Suite 200 San Diego, CA 92130 Telephone (858) 792-1235 FAX (858) 792-1236

DEVICE NAME

Classification Name:	Single/multiple component metallic bone fixation appliances and accessories
Trade/Proprietary Name:	APTUS® Titanium Fixation System
Common Name:	Plate, Fixation, Bone

DEVICE CLASSIFICATION

FDA has classified bone fixation plates as Class II devices (21 CFR 888.3030). The product code for bone fixation plates is HRS. This device classification is reviewed by the Orthopedic Devices Branch.

INTENDED USE

The APTUS® Titanium Fixation System is intended for use in hand and forearm fractures, osteotomies and arthrodeses.

DEVICE DESCRIPTION

The APTUS® Titanium Fixation System consists of implant plates and implant screws and is used for internal fixation of small bones.

APTUS Plates

Implant Modules are provided in sizes Hand 1.2, Hand 1.5, Hand 2.0, Hand 2.3 for various finger segments. The distal radius reconstruction plate system is used for fixation of fractures of the distal radius and for corrective osteotomies of the distal radius with palmar or dorsal surgical access. Variations of plate shapes include H frame, straight, T and L shaped.

APTUS Screws

Locking screws for the Radius and Hand 2.0 Lock product lines, designated TriLock™, utilize a spherical three point wedge locking design and are used with locking plates. Conventional bone screws have a double thread design and precisely cut sharp thread profile, tapering core diameter and atraumatic tip. The shorter screws have a small pitch in order to maintain optimal purchase in the bone, while the longer screws have a larger pitch in order to minimize the number of revolutions.

EQUIVALENCE TO MARKETED PRODUCT

The APTUS® Titanium Fixation System is substantially equivalent in indications and design principles to the following predicate devices, each of which has been determined by FDA to be substantially equivalent to pre-amendment devices: Profyle™ Titanium Hand and Small Fragment System (K961497) from Howmedica (Stryker); Stryker® Leibinger Universal Distal Radius System (K040022) from Stryker Leibinger; and Distal Radius Fracture Repair System (K002775, K023007, K030198) and Fragment Plate System (K041081) from Hand Innovations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 3 2005

Medartis, Inc.
c/o Mr. Floyd G. Larson
President
PaxMed International, LLC
11234 El Camino Real, Suite 200
San Diego, California 92130

Re: K051567
Trade/Device Name: APTUS® Titanium System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: June 13, 2005
Received: June 14, 2005

Dear Mr. Larson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

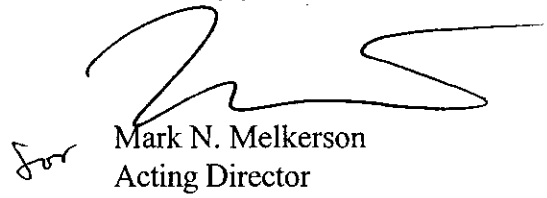
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051567

Device Name: APTUS® Titanium Fixation System

Indications for Use:

The APTUS® Titanium Fixation System is intended for use in hand and forearm fractures, osteotomies and arthrodeses.

APTUS® Hand group:

- Management of the fractures of the distal, middle and proximal phalanges and metacarpals
- Management of all types of transversal fractures, spiral fractures, fractures near joints with or without joint involvement, shaft factures, comminuted fractures, dislocation fractures, avulsion fractures
- DIP and PIP arthrodoses

APTUS® Radius 2.5 group:

- Management via radio volar approach of extra-articular extension and flexion fractures, articular extension and flexion fractures, correction osteotomies for badly healed radius fractures
- Management via dorsal approach of rare extension fractures that cannot be adequately reduced via volar approach, procedures for which the soft tissue conditions make a volar approach very difficult or impossible, correction osteotomies requiring stabilization from the dorsal side, carporadial fusions.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K051567